DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2597n

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

April 20, 1999

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Horizon Dairy
21802 South Lindsay Road
Chandler, AZ 85249

W/L 29-9

Attn: Jeff E. Blevins, Owner

Dear Mr. Blevins:

An investigation at your dairy operation located at 21802 South Lindsay Road, Chandler, Arizona, conducted by our investigator on March 8 to 10, 1999, confirmed that you offered animals for sale for slaughter as food in violation of Section 402 (a)(2)(C)(ii), and 402 (a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

On or about the October 30, 1998, you sold a culled dairy cow identified by USDA report #259514 for slaughter as human food at [redacted], USDA analysis of tissue samples collected from that animal identified the presence of streptomycin in the kidney at 11.00 ppm. A tolerance of 2.00 ppm has been established for residues of streptomycin in the edible tissues of cattle. The presence of streptomycin above the established tolerance in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack the conditions of an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals treated by you have been withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The following new animal drugs found on your premises, are adulterated under Section 501(a)(5) of the Act, when they are used, as was indicated to our investigator, in a manner contrary to their approved labeling:

1. Injectable penicillin G procaine is labeled for a dosage of 1cc/100 lbs with a maximum of 10 ccs per injection site. Your use of 60 - 80 ccs per cow as well as the administration of 15 - 20 ccs per injection site is greater than labeled and causes the drug to be unsafe to use.

2. Injectable oxytetracycline HCL, such as Durvet's Duramycin is labeled for a dosage of 3-5 cc/100 lbs and not for use in lactating dairy animals. Your administration of 150 ccs to lactating cattle is contrary to the labeled directions and causes the drug to be unsafe to use.

While a licensed veterinarian, under certain well-defined circumstances, may administer or prescribe drugs in a manner not approved in the labeling, such authority has not been extended to non-veterinarians under any circumstances.

The above is not intended to be an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

Your should take prompt action to correct the above violations and to assure that the procedures you have established will prevent their recurrence. Failure to do so may result in regulatory action without further notice, such as injuction.

Please note that it is not necessary for you to personally ship adulterated animals in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

Please advise this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your dairy into compliance with the law. Your response should include each step that has been taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which such corrections will be made.

Your response should be directed to:

Thomas Sawyer, Director of Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612

Sincerely

Thomas Sawyer, for

Elaine C. Messa
District Director